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GB 1486562 A GB 1392945 A GB 0234590 A
EP 0013534 A1 US 5042467 A US 4291688 A

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(54) Inhaler

(57) An inhaler for powdery or fluid medicaments has a mouthpiece 40 fitted with a siren or similar means for generating a sound indicative of the flow of inhaled air through the mouthpiece. The mouthpiece may be detachable from the rest of the inhaler and may have a radially-extending annular flange to prevent swallowing. The inhaler allows a user to ensure the optinum rate of inhalation of the medicament by listening to the sound made and can be used to teach children how to inhale properly.

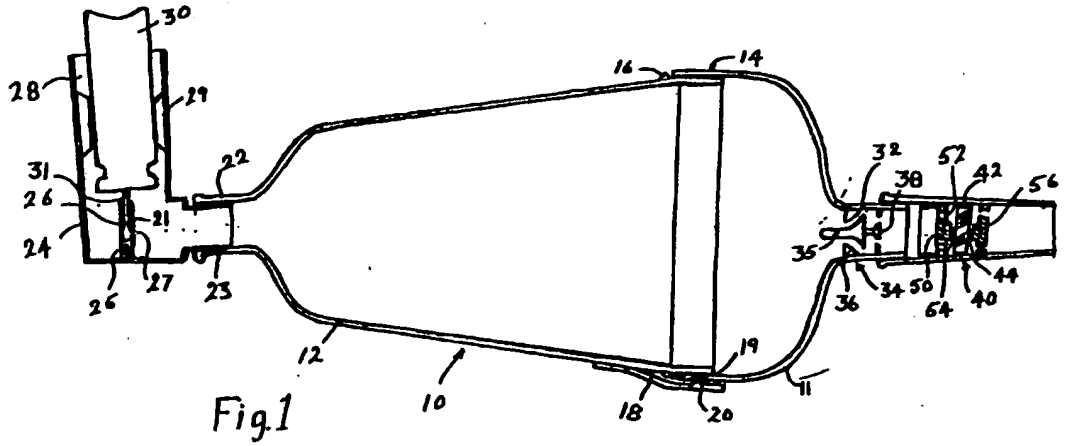

Fig.1

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At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

The claims were filed later than the filing date within the period prescribed by Rule 25(1) of the Patents Rules 1995

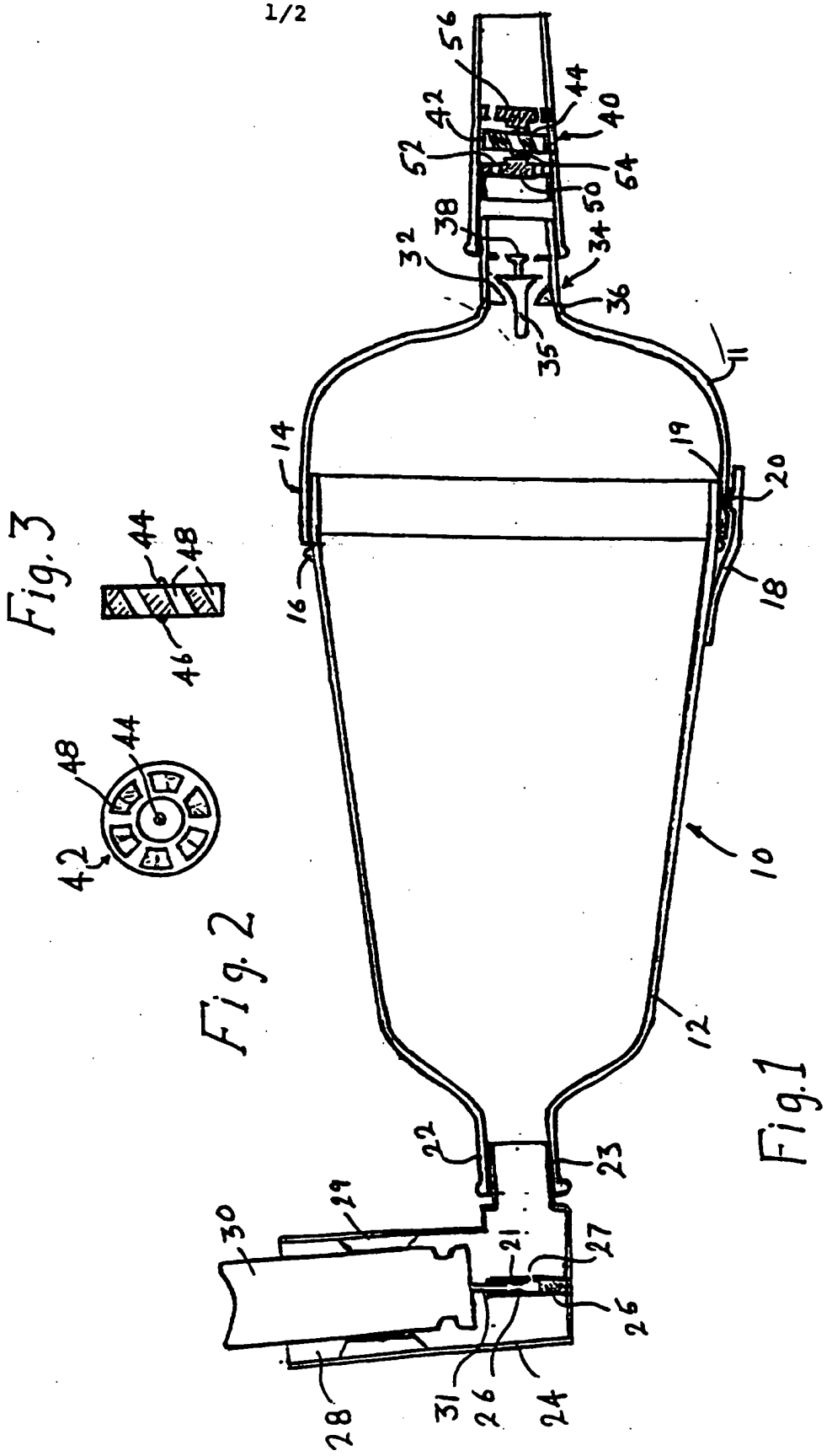
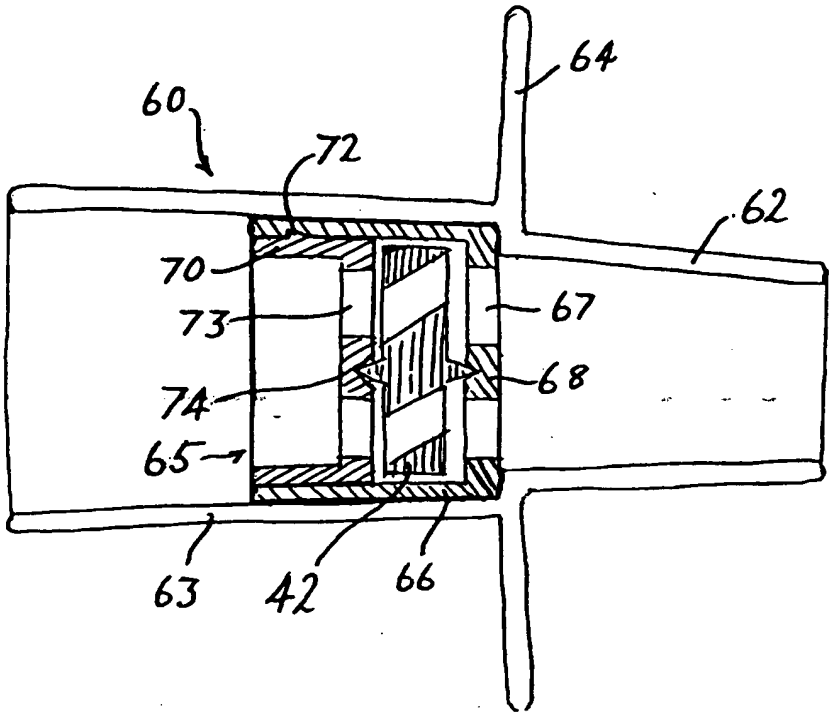


Fig. 1

Fig. 3

Fig. 2

Fig. 4



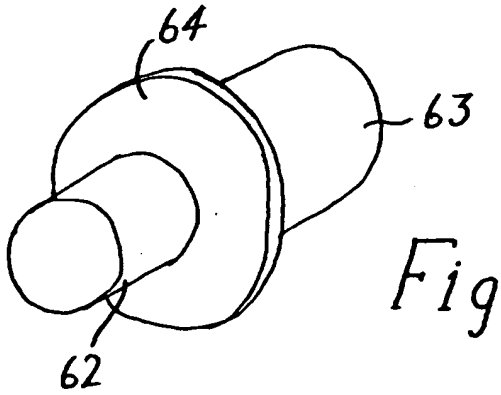


Fig. 5

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INHALER

This invention relates to an inhaler of the type used for example by asthmatics to inhale bronchial dilators.

Asthma is an allergic condition which, in response to the inhalation of certain foreign proteins such as pollen or the excreta of house dust mites, causes constriction of the bronchial passages of a patient, resulting in breathing difficulties.

Asthmatic attacks can be relieved or prevented by inhalation of a bronchial dilator such as salbutamol.

Various types of inhaler are available to enable a patient to inhale a measured amount of a bronchial dilator in powder form. In one form of inhaler, a prescribed dose of the powder is provided in a pharmaceutical capsule. The inhaler is dismantled to allow insertion of a capsule, which is then crushed upon reassembly of the inhaler to release the required dose. This is then inhaled through a mouthpiece, the powder passing between the blades of a rotor which is caused to spin by the air being drawn through the mouthpiece. The rotating blades of the rotor help to break up any lumps of the powder to ease inhalation.

Inhalers of this type have various problems however. If the capsules have not been stored in sufficiently dry conditions they may be squashed but not

broken sufficiently to release all the powder. Also the powder itself may not be evenly distributed in the inhaled airstream, particularly if the powder is not completely dry. This can result in powder remaining in the mouth and eventually being swallowed rather than properly inhaled. Retention in the mouth can cause mouth ulcers.

These problems become particularly acute in the case of very small children, since it is difficult for them to learn how to inhale properly, and they may blow rather than suck, or suck intermittently in such a way that the full dose of powder is not inhaled.

To help solve some of these problems, it has been proposed to provide the powdered dilator in a cartridge under compression with a valve arranged to deliver a metered dose of the powder when the cartridge is pressed against an anvil. The dose can be directed through an orifice into one end of an expansion chamber at the opposite end of which is a mouthpiece. A one-way valve may also be provided upstream of the mouthpiece. Such a cartridge can keep the powder dry, and the expansion chamber ensures improved dispersal in the inhaled air. Such an inhaler is reasonably easy for adults to use but it may still be difficult to judge how hard to inhale, or to coordinate inhalation with the injection of the powder for maximum effect. Such inhalers are still very difficult to use with young children. Their hands are usually not strong enough, or even big enough, to operate the powder

injection, so that this has to be done by an adult. It is however still difficult to get the child to inhale properly, and to coordinate the injection of the powder. As a result powder may simply be left coating the inside of the expansion chamber rather than being inhaled.

The present invention provides an inhaler for powdery or fluid medicaments comprising a mouthpiece and means for delivering the medicament to the mouthpiece, wherein the mouthpiece is fitted with means for generating a sound indicative of the flow of inhaled air through the mouthpiece. The invention also provides a detachable mouthpiece, incorporating such sound generating means, for use on an inhaler of the aforementioned type.

The sound generating means is preferably in the form of a siren, of the type wherein a small perforated disc is rotatably mounted adjacent a fixed perforated screen and caused to rotate relative to the screen whenever air is drawn through it. Sirens of this type are widely available as toys. The sound made by the siren increases in pitch as the rate of flow of air through it increases, so that with practice the user can judge the optimum rate of inhalation by listening to the sound made.

The inhaler is preferably of the type wherein inhalation is coordinated with the injection of powder, which may be through an expansion chamber. Such an inhaler is particularly suited for use by young children, who can be taught to inhale through the mouthpiece to produce the

correct sound. They can be given the mouthpiece, with the siren inside it, to practice with separately from the rest of the inhaler. When the inhaler is being used by a young child, the supervising adult can judge, from the sound made by the siren, the correct moment to inject the powder into the expansion chamber for maximum effect.

A preferred embodiment of the invention will now be described with reference to the accompanying drawings wherein:

FIG. 1 is a side view, partly in cross section, of an inhaler in accordance with a first embodiment of the invention;

FIG. 2 is an enlarged view of the siren rotor of Fig. 1, in the direction of its axis of rotation; and

FIG. 3 is an enlarged side view of the rotor, at right angles to that of Fig. 2.

FIG. 4 is an enlarged cross-sectional view of a mouthpiece in accordance with a second embodiment; and

FIG. 5 is a perspective view of the mouthpiece of Fig. 4.

Referring first to Fig. 1, an inhaler comprises an expansion chamber 10 made of any suitable transparent rigid plastics material, for example polymethylmethacrylate. The expansion chamber is elongate and of generally circular cross section, with a neck 22 at one end to receive a corresponding fitting 23 of an injector mounting 24, and a neck 32 at the opposite end, coaxial with the neck 22, to

receive a mouthpiece 40. The main body of the expansion chamber is tapered, its cross sectional area increasing in a direction from the injector to the mouthpiece.

For ease of cleaning, the expansion chamber is in two separable parts 11 and 12, with respective cylindrical surfaces joining by a friction fit at 14. A circumferential rib 16 limits the distance by which the part 12 can slide over the part 11.

The two parts of the expansion chamber are secured together by snap-fitting clips, of which one is shown at 18. This simply comprises a strip of resilient plastics material secured to the expansion chamber part 10 and having an inwardly facing projection 20 which snaps into a corresponding recess 19 on the circumference of the part 11.

The injector fitting 24 may be of conventional type, with a pipe stub 23 being received with a friction fit into the neck 22. At right angles to the pipe stub is an open ended chamber 28 which holds a cartridge 30 containing under pressure the powder to be inhaled. The cartridge is held in place by inwardly projecting ribs 29, on the inner surface of the holder, leaving free space around the cartridge through which air can be drawn into the expansion chamber.

At the lower end of the cartridge as seen in the drawing there projects a narrow tube 31 connected to a dispensing valve inside the cartridge. This tube projects

into a tube 21, integrally formed in a pillar 25 projecting upwardly from a bottom surface of the holder. Within the tube 26 is a constriction 21 past which the tube 31 cannot be pushed and which thus acts as an anvil. At the lower end of the tube 26 is an orifice 27, at right angles to the axes of the tubes 26 and 31 and aligned with the longitudinal axis of the expansion chamber. Thus, when pressure is applied to the upper end of the cartridge, pushing it downwardly against the constriction 26, the dispensing valve is actuated and a metered amount of powder is sprayed through the orifice 27. If this action is coordinated with an intake of air through the holder into the expansion chamber, the powder is evenly distributed into the air entering the chamber.

At the opposite end of the expansion chamber, within the neck 32, there is provided a non-return valve generally indicated by 34. This comprises a conical valve member 35 slidably mounted on a post 38 which in turn is fixedly mounted within the neck 32. The conical valve member 35 and post 38 are both coaxial with the neck 32, the expansion chamber and the neck 22. If air is blown into the expansion chamber through the neck 32, the valve member 35 seats itself against an annular valve seat 36 to prevent the further entry of air. If air is drawn in the opposite direction, out of the expansion chamber, the valve member is lifted clear of its seat to allow the free passage of air.

The mouthpiece 40 is of generally cylindrical shape but tapering slightly in a direction away from the expansion chamber. It is releasably attached to the neck 32 by a friction fit.

Within the mouthpiece 40, there is provided a siren comprising a rotor 42 mounted between two fixed bearings. Of these, a bearing 56 may be integrally molded with the mouthpiece, and may comprise a perforated disc or simply a central hub mounted on radial spokes. At its centre it has a small recess to receive a small conical projection from the centre of rotor 42. A similar projection 46 on the opposite side of the rotor, coaxial with projection 44, is received in a corresponding recess 54 in a perforated disc 50 which is cup-shaped and pushed into the mouthpiece as far as it will go to achieve a friction fit, so that the rotor 42 is held between the two bearings thus formed and able to spin freely. The disc 50 has perforations 52, suitably circular holes, spaced circumferentially around the rotor bearing at regular intervals.

The rotor 42 and disc 50 may be made of any suitable plastics material such as polypropylene.

The rotor 42 is shown in more detail in Figs. 2 and 3. It can be seen that it has six apertures 48 extending through the disc-shaped rotor and spaced uniformly and circumferentially around the rotor axis. Each of the apertures 48 extends at an acute angle relative to the rotor axis so that as air is drawn through it the rotor

will rotate and, because of its proximity to the perforated disc 50 and its fixed mounting 56, will generate a whistling sound, the pitch of which will vary according to the rate of air flow.

The spacing between the components of the siren is slightly exaggerated in the drawing for the purposes of clarity. In practice, the spacing between the rotor 42 and perforated disc 50 will preferably be in the range from 0.5 to 2 mm, although smaller or larger spacings will suffice provided a suitable sound is still generated.

By making the two mountings for the rotor of different configurations, the siren may be made to generate a slightly different sound according to the direction of air flow through it. In this way, a supervising adult can tell if a child is blowing rather than sucking through the mouthpiece.

To use the inhaler, the mouthpiece is held within the mouth and air is inhaled at a steady rate from the expansion chamber. The flow of air causes the rotor 42 to rotate, generating a whistling sound. When a sustained noise of the correct pitch is achieved, the cartridge 30 is pressed down against the anvil formed by constriction 26 and a metered dose of powder is squirted out through the nozzle 27 and carried into the expansion chamber by air flowing in around the outside of the cartridge. As the powder passes through the expansion chamber it is distributed throughout the airflow, passing through the

one-way valve and the siren 40. The process of mixing the powder into the airflow is further assisted by passing through the rotor 42 of the siren.

Other embodiments of the invention are envisaged. For example, the siren rotor could be in the form of a bladed fan rather than a perforated disc, provided it was positioned close enough to a fixed perforated screen to generate a suitable sound. The inhaler could be used not just for medicaments in powder form, but for fluid medicaments which would be atomised and dispersed in the same way as the solid powder.

The expansion chamber illustrated might suitably have a length of about 30 cm and a diameter of about 10 cm., which enables the injected powder to be dispersed so finely in the inhaled air that the otherwise rather disagreeable taste is scarcely noticed. The chamber could however be made considerably smaller in order to make the device more compact and portable, and could indeed be dispensed with altogether, the injector being linked to the siren-containing mouthpiece by a short length of pipe or the like so that the whole device could easily be carried in a coat pocket or school bag. The powder may then be dispersed in a smaller volume of air, but it is still atomised and passage through the siren helps to ensure that there is no aggregation of powder particles as they are inhaled.

The mouthpiece shown in Figs. 4 and 5 could be

fitted to an expansion chamber such as that shown in Fig. 1, or directly to the pipe stub 23 of an injector 24 such as that shown in Fig. 1, or otherwise connected to suitable powder injecting means through a desired intermediate portion such as a short length of tube. This mouthpiece 60 has a tapered portion 62 intended to be received in the mouth, this portion being integral and coaxial with a longer portion 63 which is slightly less tapered and is intended to be connected to an injector, expansion chamber or other suitable means intended to convey powder to the mouthpiece.

Between the portions 62 and 63 is a radially extending annular flange 64 which acts as a guard to prevent accidental swallowing of the mouthpiece.

Within the mouthpiece section 63 is a siren generally indicated by 65. This siren differs from that shown in Figs. 1 to 3 in that it is made up as a complete unit before insertion into the mouthpiece. The siren comprises an outer cup member 66 which is received in the mouthpiece section 63 with a friction fit and has at one axial end a bearing 68 to receive a siren rotor 42, similar to that of Figs. 1 to 3, the bearing 68 being surrounded by apertures 67 distributed uniformly around it.

The other side of the rotor 42 is held in place by a bearing 74 of a securing member 70 which is also cup-shaped but of shorter axial length than the member 66 and which is retained in the latter by a press-fit, with the

engagement of peripheral teeth or ribs 72 in a corresponding recess or annular channel on the inner surface of the cup-shaped member 66.

Inhalers in accordance with the invention can be used in three principal ways. First, with a mouthpiece fitted directly, or in close proximity, to a powder injector the whole inhaler is rendered easily portable and can still be used to gauge, by sound, when inhalation is at its peak. A metered dose of powder can then be released at the optimum moment to constitute a proper dose.

When inhalation is taking place under supervision, the device can be fitted to an expansion chamber. The person supervising is then able to judge how many breaths the patient has taken, and of what magnitude. This is important when administering treatment to the very young and very old. The timing of the injection is less important when using the expansion chamber, since the injected dose can be inhaled in more than one breath.

Thirdly, the mouthpiece of the invention, which is preferably detachable from the other components of the inhaler, can be used to teach an infant to inhale. It has been found that an 18 month old infant can very quickly learn how to inhale air through the mouthpiece, to which the rest of the inhaler can be fitted once the child has learnt to inhale.

CLAIMS:

1. An inhaler for powdery or fluid medicaments, comprising a mouthpiece and means for delivering the medicament to the mouthpiece, wherein the mouthpiece is fitted with means for generating a sound indicative of the flow of inhaled air through the mouthpiece.

2. An inhaler according to claim 1 wherein the sound generating means is a siren comprising a perforated disc rotatably mounted adjacent a fixed perforated screen and caused to rotate relative to the screen when air is drawn through it.

3. An inhaler according to claim 1 or claim 2 wherein the means for delivering the medicament to the mouthpiece comprises an injector.

4. An inhaler according to claim 3 wherein the injector is separated from the mouthpiece by an expansion chamber.

5. An inhaler according to any preceding claim wherein the mouthpiece and its associated sound generating means are detachable together from the rest of the inhaler.

6. An inhaler according to any preceding claim wherein the mouthpiece is fitted with a radially extending annular flange to prevent swallowing of the mouthpiece.

7. A mouthpiece for attachment to an inhaler for powdery or fluid medicaments, said mouthpiece being fitted with means for generating a sound indicative of the flow of inhaled air through the mouthpiece.

Patents Act 1977
Examiner's report to the Comptroller under Section 17
The Search report)

Application number
GB 9507133.8

Relevant Technical Fields

(i) UK Cl (Ed.N) A5T (TBD, TBE, TBC, TED) G5J (JWWW)

(ii) Int Cl (Ed.6) A61M 15/00

Search Examiner
MR N A FRANKLIN

Date of completion of Search
27 SEPTEMBER 1995

Databases (see below)
(i) UK Patent Office collections of GB, EP, WO and US patent specifications.

(ii) ONLINE: WPI

Documents considered relevant following a search in respect of Claims :-
1-7

Categories of documents

X: Document indicating lack of novelty or of inventive step.

Y: Document indicating lack of inventive step if combined with one or more other documents of the same category.

A: Document indicating technological background and/or state of the art.

P: Document published on or after the declared priority date but before the filing date of the present application.

E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.

&: Member of the same patent family; corresponding document.

Category	Identity of document and relevant passages		Relevant to claim(s)
X	GB 1486562	(HILARY PAGE) note sound-producing mouthpiece 4 in Figure 1	7
X	GB 1392945	(FISONS) note Claim 3	1, 2
X	GB 234590	(CLAFF) note sound-producing mouthpiece 3 in Figure 1	7
X,Y	EP 0013534 A1	(SCHERICO) note page 3 lines 1-9 and page 9 line 21 to page 10 line 7	X:1, 3, 4 Y:2
X,Y	US 5042467	(FOLEY) note column 2 lines 4-31, column 5 lines 16-36	X:1, 3-5 Y:2
X,Y	US 4291688	(KISTLER) note column 1 lines 34-43	X:1, 3, 4 Y:2

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